



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/647,518	11/30/2000	Martin Fricde	B45139	8200

20462 7590 08/22/2003

SMITHKLINE BEECHAM CORPORATION
CORPORATE INTELLECTUAL PROPERTY-US, UW2220
P. O. BOX 1539
KING OF PRUSSIA, PA 19406-0939

EXAMINER

CEPERLEY, MARY

ART UNIT	PAPER NUMBER
----------	--------------

1641

DATE MAILED: 08/22/2003

14

Please find below and/or attached an Office communication concerning this application or proceeding.

Advisory Action

Application No.

09/647,518

Applicant(s)

FRIEDE ET AL

Examiner

Mary (Molly) E. Ceperley

Art Unit

1641

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 13 August 2003 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE. Therefore, further action by the applicant is required to avoid abandonment of this application. A proper reply to a final rejection under 37 CFR 1.113 may only be either: (1) a timely filed amendment which places the application in condition for allowance; (2) a timely filed Notice of Appeal (with appeal fee); or (3) a timely filed Request for Continued Examination (RCE) in compliance with 37 CFR 1.114.

PERIOD FOR REPLY [check either a) or b)]

- a) ☒ The period for reply expires 6 months from the mailing date of the final rejection.
- b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection. ONLY CHECK THIS BOX WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

1. ☐ A Notice of Appeal was filed on _____. Appellant's Brief must be filed within the period set forth in 37 CFR 1.192(a), or any extension thereof (37 CFR 1.191(d)), to avoid dismissal of the appeal.
2. ☒ The proposed amendment(s) will not be entered because:
- (a) ☒ they raise new issues that would require further consideration and/or search (see NOTE below);
- (b) ☐ they raise the issue of new matter (see Note below);
- (c) ☒ they are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
- (d) ☐ they present additional claims without canceling a corresponding number of finally rejected claims.

NOTE: See the attached letter.

3. ☐ Applicant's reply has overcome the following rejection(s): _____.
4. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
5. ☒ The a) ☐ affidavit, b) ☐ exhibit, or c) ☒ request for reconsideration has been considered but does NOT place the application in condition for allowance because: See the attached letter.
6. ☐ The affidavit or exhibit will NOT be considered because it is not directed SOLELY to issues which were newly raised by the Examiner in the final rejection.
7. ☒ For purposes of Appeal, the proposed amendment(s) a) ☒ will not be entered or b) ☐ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.

The status of the claim(s) is (or will be) as follows:

Claim(s) allowed: _____.

Claim(s) objected to: 58.

Claim(s) rejected: 38-64.

Claim(s) withdrawn from consideration: _____.

8. ☐ The proposed drawing correction filed on _____ is a) ☐ approved or b) ☐ disapproved by the Examiner.
9. ☐ Note the attached Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____.
10. ☐ Other: _____.

Mary (Molly) E. Ceperley
Primary Examiner
Art Unit: 1641

1) The amendment filed August 13, 2003 under 37 CFR 1.116 in reply to the final rejection has been considered but is not deemed to place the application in condition for allowance and will not be entered because the proposed amendment is not deemed to place the application in better form for appeal by materially simplifying the issues for appeal. The proposed claim 38 limitation of "and at least one immunostimulant" raises new issues that would require further consideration and/or search.

- One new issue is that fact that the words "immunostimulant" and "adjuvant" are synonymous in the art. Page 3, lines 19-21 of the instant specification state that the polyoxyethylene ether or ester "adjuvants" of the instant invention "are able to significantly enhance the systemic immune response towards co-administered antigens". This is exactly the same function provided by an "immunostimulant". Thus, it is not clear that the added "immunostimulant" is, in fact, a different component than the "adjuvant".
- A second issue is that it is unclear what is meant to be encompassed by the term "immunostimulant". In their Remarks, applicants present no discussion of where this term is supported in the specification or what scope is intended.
- A third issue is that although applicants state that Modi et al "neither disclose nor suggest a composition having at least one immunostimulant", applicants have neither supported this statement with a discussion of Modi et al nor provided any reasoning as to why the added "immunostimulant" (adjuvant?) of the instant claims would not be considered to ^{be} a conventional vaccine component.

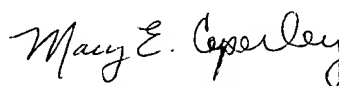
2) A newly presented amendment limited to the corrections described in paragraph **1)** of the final rejection and to the cancellation of claim 58 would be entered.

3) Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mary E. (Molly) Ceperley whose telephone number is (703) 308-4239. The examiner can normally be reached from 8 a.m. to 5 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le, can be reached at (703) 305-3399. The fax phone number for responses to be filed BEFORE final rejection is (703) 308-4556. The fax phone number for responses to be filed AFTER final rejection is (703) 305-3592.

Questions which are NOT RELATED TO THE EXAMINATION ON THE MERITS, should be directed to **TC 1600 CUSTOMER SERVICE** at **(703) 308-0198**. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

August 22, 2003


Mary E. (Molly) Ceperley
Primary Examiner
Art Unit 1641